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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,341	06/21/2005	Scott Eugene Conner	X-15463	1424
25885 7590 01/02/2009 ELI LILLY & COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288				
EXAMINER				
CHU, YONG LIANG				
ART UNIT		PAPER NUMBER		
1626				
NOTIFICATION DATE		DELIVERY MODE		
01/02/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

### Office Action Summary

**Application No.**

10/540,341

**Applicant(s)**

CONNER ET AL.

**Examiner**

YONG CHU

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 October 2008.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 54, 56-58 and 68-70 is/are pending in the application.  
4a) Of the above claim(s) 56-58 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 54 and 68-70 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/07/2008 has been entered. Upon entering the submission, claims 54, 56-58, and 68-70 are pending. Claims 56-58 remain withdrawn as non-elected subject matter. Claim 54 and 68-70 are examined together on the merits.

### *Response to RCE Submission*

#### **Claim rejection under 35 U.S.C. §102**

The rejected claims 2, 35-37, 41, and 43-44 have been cancelled, and the rejection over the claims is moot. Applicants' amendment of the rejected claim 54 has obviated the rejection.

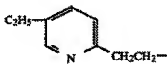
#### **Claim rejection under 35 U.S.C. §103(a)**

Applicants' argument and amendment over the rejection of claims 68-70 under 35 U.S.C. §103(a) have been fully considered, but are found not persuasive. Applicants argue that two differences are present between the instantly claimed compounds and the cited prior art compound: the alkyl-substituted alkoxy linker vs. non-substituted alkoxy linker; and propyl-substituent pyrazole group vs. methyl-substituent pyrazole group. In addition, Applicants

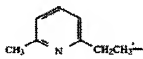
Art Unit: 1626

argue that “the required alkyl substitution in the linker region to provide PPAR delta activity in an unexpected advance in the art”, see p. 5 under Remarks in the reply. Finally, Applicants correlate the instant rejection to the Takade Chemical v. Alpharpharm case, wherein the Court found that a compound with methyl vs. ethyl, and ring walking on the pyridyl ring over the prior art compound b is not obvious.

Applicants’ arguments are not persuasive. In the Takade case, the Court states “that generalization should be avoided insofar as specific chemical structures are alleged to be prima facie one form from the other,...”. The Takade case can not be correlated to the instant rejection, even though the compounds in the two cases both have two differences. It is because the non-obvious



Takade compound with the moiety is a FDA approved drug called ACTOS® or Pioglitazone with nontoxicity, while the alleged prior art



“compound b” with the moiety shows negative side effects of increasing body weight and brown fate, which renders the compound b “presumably not” be a suitable candidate compound for the claimed utility, see Takade Chemical v. Alpharpharm, 83 USPQ2d, 1176. Because of this unexpected non-toxic result of the Pioglitazone compound over the “compound b”, the Court rules that the two compounds are not obvious. Different from the Takade case, the instantly cited prior art `858 application demonstrates the

Art Unit: 1626

biological activity of the claimed compounds in TABLE 1-4, pages 35-37, while the instant application does not disclose **any** unexpected results over the prior art teaching. Furthermore, the instant application even does not disclose **any** **evidence or data** to support the claimed utility, except a general statement of the utility, which has been taught by the prior art, which is indeed not unexpected results. Therefore, the instant claims would be obvious over the prior art teaching, and the rejection is maintained.

To overcome the rejection, Applicants have to demonstrate the true unexpected results over the prior art teaching under Declaration, such as less side-effect, or much better activity toward the claimed utility (i.e. treating diabetes).

### ***Conclusion***

No claim is allowed.

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1626

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong Chu/  
Patent Examiner  
Art Unit 1626